

REMARKS

35 USC Section 112, second paragraph

Claim 25 is rejected under 35 USC Section 112, second paragraph as being indefinite.

In order to expedite prosecution, claim 25 is amended herein to refer to "huMAb4D5-8" as supported on page 10, line 25, for example, thus obviating the rejection. Reconsideration and withdrawal of the Section 112, second paragraph rejection is respectfully requested.

35 USC Section 103

Claims 21, 25 and 26 are rejected under 35 USC Section 103 as being unpatentable over any Baselga et al. *J. Clin. Oncol.* 14(3): 737-744 (1996) ("Baselga I"), or Baselga et al. *Semin. Oncol.* 4(12): 78-83 (1999) ("Baselga II") in view of Pauletti et al. *Oncogene* 13: 63-72 (1996), or Persons et al. *Annals. Of Clinical and Laboratory Science* 30(1):41-48 (2000).

Claim 1 is amended herein to refer to state that the "patient's tumor cells express HER2 at a 0 or 1+ level by immunohistochemistry" as supported, for example, on page 28, lines 27-29.

The present invention provides an improved method for screening for, and treating, breast cancer patients, wherein patients with her2 gene amplification are treated with a HER2 antibody. This method is not disclosed or suggested by the cited references. Baselga I and Baselga II describe therapy of patients whose metastatic breast carcinomas overexpress HER2 as determined by IHC (see *Selection of Patients* in column 1 on page 738 of Baselga I, and *Patients* in columns 1-2 on page 79, Baselga II). Pauletti concerns FISH for clinical prognosis (abstract of Pauletti), and Persons studied HER2 amplification as a prognostic and predictive marker (summary paragraph in column 2. on page 47 of Persons), rather than detecting her2 gene amplification in tumor cells in order to identify and treat a patient disposed to respond favorably to a HER2 antibody.

Applicants submit that the presently claimed invention and its unexpected advantages for better selecting patients who can benefit from therapy with a HER2 antibody are neither disclosed nor suggested in the cited art. Reconsideration

Serial No.: 09/863,101

and withdrawal of the Section 103 rejection is respectfully requested.

IDSs

Applicants note that initialed copies of the PTO 1449 forms from the July 21, 2003 IDS (citing ref. No. 319) and August 20, 2004 IDS (citing ref. Nos. 320-349) had not been returned to them. Examiner Holleran said at the interview that a copy of the August 2004 IDS was in the PTO's file, but she could not locate a copy of the PTO-1449 or reference from the July 2003 IDS. Accordingly, Applicants attach a courtesy copy of the 2003 IDS, PTO-1449 form and cited reference for the Examiner's convenience. Applicants respectfully request that the initialed PTO 1449 forms be returned, completing the Office's review of all cited art.

Respectfully submitted,
GENENTECH, INC.

Date: November 9, 2004

By: Wm Lee
Wendy M. Lee
Reg. No. 40,378
Telephone: (650) 225-1994